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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,032	11/20/2003	Timothy A. Geiser	ACS 58145 (3166P)	2537

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EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	**PAPER NUMBER**
3731	

MAIL DATE	DELIVERY MODE
06/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,032	GEISER ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-30,32-34 and 47-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-30,32-34 and 47-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/12/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

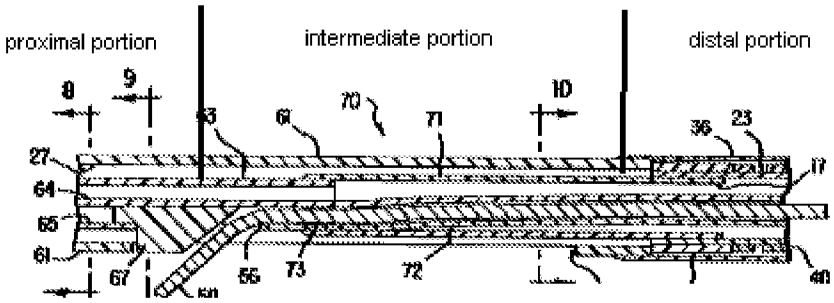
Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. **Claims 26-30, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell (USPN 5,792,144).**

2. Fischell discloses (with respect to claim 1) a catheter assembly comprising: a control handle (Fig. 1); an inner catheter (for purposes of example 23, 71, 72, 63, 11, 12) member having a proximal end and a distal end and further including a distal mounting portion (23, Fig. 7) adapted to have a medical device mounted thereon (40), the proximal end attached to the control handle, and a guide wire receiving member (72) having a proximal end and a distal end and being configured for receiving a guide wire (50, see Fig. 7), the proximal end of the guide wire receiving member being spaced apart from the proximal end of the inner catheter member (see Fig. 7 for proximal end of guidewire receiving member and see Fig. 1 for example for proximal end of inner catheter member, note that Fig. 1 is used for illustrative purposes as having the same design as Fig. 7 C7:39-43), the guide wire receiving member further including an opening at the proximal end (for example 66, fig. 7) and an opening at the distal end (for example 19, fig. 1) and a lumen extending between these openings formed on the distal and proximal ends of the guide wire receiving member; and an outer catheter member (for example 30, 32, 34, 36) co-axially disposed over the inner catheter member and dimensioned for relative axial movement relative to each other (C 5:L38-45; Fig. 3), the

outer catheter member being comprised of multiple portions (see below), wherein the outer catheter member includes a distal portion having a proximal end and a distal end, the distal portion being adapted to at least partially cover the medical device (see Figs. 1, 6, 7), the distal portion having an inner surface which directly contacts the medical device (C6:L1-4; see Fig. 1), an intermediate portion having a distal end and a proximal end, the distal end of the intermediate portion coupled to the proximal end of the distal portion, and a proximal outer member having a proximal end and a distal end, the proximal end of the proximal outer member being attached to the control handle and a the distal end of the proximal outer portion being coupled to the proximal end of the intermediate portion,



wherein the proximal end (for example 66) of the guide wire receiving member is received in an opening (for example slot 62 and the lumen associated with slot 62) formed at the proximal end of the intermediate portion of the outer catheter member.

27. wherein the intermediate portion of the outer catheter member includes a lumen and the proximal end of the guide wire receiving member is slidably disposed within this lumen (C 5:L38-46).

28, wherein the distal mounting portion (23) of the inner catheter member has a lumen (for example 17) extending therethrough and a portion of the guide wire member extends through this lumen (See Fig. 7).

29. wherein the portion of the guide wire receiving member extending through the lumen of the distal mounting portion is secured to the wall forming the lumen (via element 71).

30 and 32 wherein the portion of the guide wire receiving member (proximal portion) which does not extend through the lumen of the distal mounting portion is slidably disposed within the lumen (27) of the intermediate portion of the outer catheter member (C5:L38-46).

Claim Rejections - 35 USC § 103

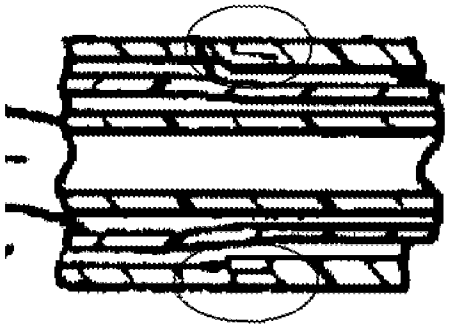
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 47-52, 54-65 rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (US 5,792,144).

5. With respect to claim 47, Fischell discloses all the elements as claimed as stated above specifically that the proximal end of the guidewire lumen is spaced apart from the proximal end of the inner catheter (as in Fig. 7). Fischell further discloses in a different embodiment (in Fig. 1) that the diameter of the intermediate portion being greater than

the diameter near the distal end of the proximal portion (see below), the distal end of the proximal portion being attached to the proximal end of the intermediate portion.



However Fischell does not explicitly disclose (with respect to embodiment of Fig. 7) that a passage allowing the guide wire to enter the guide wire receiving member *is formed at the area of attachment* of the proximal portion to the intermediate portion. In other words, Fischell does not explicitly disclose where the location of attachment is with respect to Fig. 7.

6. However in order to modify the Fischell device to meet this limitation would merely require the relocation of the attachment (shown above) or the relocation of the guidewire opening (62). It would have been obvious to one having ordinary skill in the art at the time of the invention to determine that changing the location of the attachment would be desirable to achieve a change in flexibility of pushability. It would have been obvious to one having ordinary skill in the art at the time of the invention to change the location of the guidewire opening depending on where the device would be delivered in the body.

7. Fischell further discloses:

48 and 58: the proximal end of the guide wire receiving member has an opening (for example 66) to the lumen of the guide wire receiving member and the proximal end of the guide wire receiving member extends into and aligns with the passage (lumen created by slot 62) formed on the outer catheter member.

49 and 50: the distal mounting portion (23) of the inner catheter member has a lumen (for example 17) extending therethrough and a portion of the guide wire member extends through this lumen (See Fig. 7).

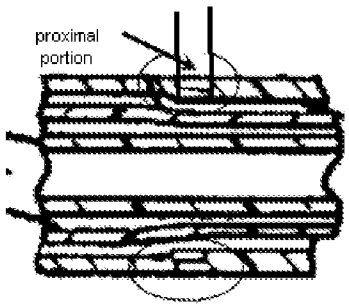
51: the inner catheter member includes a proximal portion (71 and 63 Fig. 7 and 11, 12 Fig. 1) having a proximal end and a distal end, the distal end of the proximal portion being coupled to the tubular member of the distal mounting portion.

52: the proximal portion of the inner catheter member is an elongate component.

54, 55, 56, 57, 59, 60: the portion of the guide wire receiving member (proximal portion) which does not extend through the lumen of the distal mounting portion is slidably disposed within the lumen (27) of the intermediate portion of the outer catheter member (C5:L38-46).

61: the distal end of the proximal portion extends into and is attached within the lumen of the intermediate portion of the outer catheter member (see above).

62: The entire length of the proximal portion of the outer catheter has a smaller diameter that the intermediate portion. (where proximal portion is defined as below)



63: The tubular member forming the distal end portion of the proximal portion has a tapered diameter (see above).

64: The tapered portion of the proximal portion and the proximal end of the intermediate portion cooperate to form the passage for the guide wire.

65. The proximal end of the guide wire receiving member is bent to fit within the passage formed on the outer catheter member (see for example near element 72, Fig. 7).

8. Claims 33, 34 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (USPN 5,792,144) in view Cummings (USPN 6,736,839).

9. Fischell discloses the invention substantially as claimed as stated above except for the proximal portion being formed from a hypotube. However, Cummings discloses a stent delivery device incorporating a sheath where in a hypotube is the proximal portion of the sheath or outer member (Col 3, line 60-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a hypotube into the proximal portion of the device disclosed by Fischell since it is well known in the art to use hypotubes for increased strength and pushability. It is well known in the art that hypotubes are made form stainless steel or nickel-titanium. With the incorporation of a

hypotube, the proximal portion will inherently be less flexible than the intermediate portion.

Response to Arguments

10. Applicant's arguments filed 03/12/09 have been fully considered but they are not persuasive. Applicants have amended the claims to include that the opening is formed at the proximal end of the intermediate portion. Note that for the purposes of claim 26, the intermediate portion can be any arbitrary portion of the catheter that is between the distal portion and proximal portion. Applicants amended claim 26 to require the outer catheter distal portion to have an inner surface which directly contacts the medical device. Examiner notes that while Fig 6 and 7 may show a gap, Fig 1 does not. The specification specifically states that the stent can be balloon expandable or self expanding. In the case of self-expanding, examiner asserts that the catheter distal portion would directly contact the stent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/8/09